



UNITED STATES DEPARTMENT OF COMMERCE
Pat nt and Trademark Offic

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Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/349,489	12/02/94	RING	0999.001

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HM21/1112

EXAMINER

EYLER, Y

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/12/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/349,489

Applicant(s)
Ring, David, B.

Examiner
Yvonne Eyster

Group Art Unit
1642



☒ Responsive to communication(s) filed on Aug 5, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) 4 and 9-14 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5-8, and 15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☒ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Yvonne Eyler, Group Art Unit 1642.

1. The request filed on 8/5/98 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/349489 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 1-15 are pending in the application. Claims 4 and 9-14 have been withdrawn from consideration. Claims 1-3, 5-8 and 15 are under consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

4. The use of the trademarks Quadromas^R at page 16 and Immulon^R at page 25 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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Claim Rejections Withdrawn:

5. The rejection of Claims 1-3, 5-8, and 15 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

6. The rejection of Claims 1-3, 5-8 and 15 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Claim Rejections Maintained and New Grounds of Rejection:

7. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites cancer antigens 145kD, 40kD, 60kD, 100kD, 42kD, 55kD, 66kD, 75kD, 80kD, and glycolipid which are vague and indefinite. The instant antigens cannot be unambiguously identified based solely on molecular weight under undefined conditions and chemical classification absent further definitive description. The addition of further definitive characteristics is necessary to clearly point out and distinctly claim the antigens identified.

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Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-3, 5-8 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Weiner et al. (Proc. Am. Soc. Clin. Oncol. 13, March, 1994).

Weiner et al. teach the induction of an immune response, i.e. activation of NK and LAK cells to lyse tumor cells and a HAMA response, in a patient by administration of the bispecific antibody, 2B1 in an amount equivalent to that sufficient to induce antibodies to the second, c-erbB-2 antigen. Thus, the limitations of the claimed invention are met.

10. Claims 1-3, 5-8 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Weiner et al. (Proc. Am. Soc. for Cancer Res. 35:219, March, 1994).

Weiner et al. teach the induction of an immune response, i.e. activation of NK and LAK cells to lyse tumor cells and a HAMA response, in a patient by administration of the bispecific antibody, 2B1 in an amount equivalent to that sufficient to induce antibodies to the second, c-erbB-2 antigen. Thus, the limitations of the claimed invention are met.

11. Claims 1-3, 5-8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh-Ma et al. (Cancer Research, 1992) or Weiner et al. (Cancer Research, 1993) or Ring et al.

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(Breast Epithelial Antigens, 1991) in view of Fanger et al. (Critical Reviews in Immunology, 1992) or Snider et al. (J. Exp. Med. 171:1957-1963, 1990¹⁰⁶).

Hsieh-Ma et al., Weiner et al. and Ring et al. each teach the induction of an immune response, targeted cytolysis, by administration of 2B1 as set forth in the Office Actions of 8/5/97. and 10/18/96 Weiner et al. further teach the induction of an immune response in a patient, a xenograft mouse which meets the definition of patient as specified at page 8 of the instant disclosure.

Hsieh-Ma et al., Weiner et al., and Ring et al. do not specifically teach the induction of antibody production to the second, c-erbB-2, antigen.

Fanger et al, however, teach the known method comprising administration of bispecific antibodies (and optionally antigen) to induce or enhance the production of antibodies to the second antigen. Specifically, Fanger et al. teach that bispecific antibodies targeted to APC cell antigens such as FcγRIII induce production of antibodies to the second antigen.

Similarly, Snider et al. teach a method comprising administration of bispecific antibodies (and optionally antigen) to induce or enhance the production of antibodies to the second antigen. Specifically, Snider et al. teach that bispecific antibodies targeted to APC cell antigens induce production of antibodies to the second antigen.

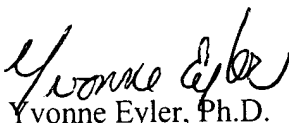
Thus, it would have been *prima facie* obvious to one of ordinary skill in the art to induce an immune response by administering antibodies to FcγRIII and a second antigen (namely 2B1) as taught by Hsieh-Ma et al, Weiner et al. and Ring et al. It would have been further obvious to one

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of ordinary skill in the art to administer the bispecific antibodies in an amount sufficient to also induce the production of antibodies to the second antigen with a reasonable expectation of success given the teachings of Fanger et al. or Snider et al. and one would have been motivated to do so to optimize the antitumor effect of the treatment.

NO CLAIM IS ALLOWED

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 600pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Yvonne Eyler, Ph.D.

Patent Examiner

November 8, 1998